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Special Review of Certain Pesticide Products Linuron: Position Document 1

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This Position Document 1 (PD 1) is the official announcement that EPA is initiating a special review of all pesticide products containing the active ingredient Linuron [3-(3,4-dichlorophenyl)-1-methoxy-1-mthylurea]. EPA has determined that Linuron is oncogenic in rats and mice and meets or exceeds the risk criterion as described in 40 CFR 162.11, the regulations governing the Special Review (RPAR) process. Only after carefully considering the risks and benefits of Captafol and determining that the pesticide will cause unreasonable adverse effects on man or on the environment, will EPA issue a notice of intent to cancel.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/41]

LINURON

SPECIAL REVIEW OF CERTAIN PESTICIDE PRODUCTS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This Notice announces that EPA is initiating a Special Review of all pesticide products containing the active ingredient linuron [3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea]. EPA has determined that linuron is oncogenic in rats and mice and meets or exceeds the risk criterion as described in 40 CFR 162.11. Accordingly, a Special Review of products containing linuron is appropriate to determine whether registration of these products should be permitted to continue and, if so, under what terms and conditions. During the Special Review process, EPA will carefully examine the risks and benefits of using linuron products and will determine the necessity for regulatory actions.

DATE: Comments, evidence to rebut the presumptions in this Notice, and other relevant information must be received on or before (insert date 45 days after date of publication in the FEDERAL REGISTER).

84P-2177

ADDRESS: Written comments identified as "OPP-30000/41," by mail to:

Information Services Section,
Program Management and Support Division (TS-757C),
Office of Pesticide Programs,
Environmental Protection Agency,
401 M St., SW.,
Washington, D.C. 20460.

In person, bring comments to:

Rm. 236, CM #2,
1921 Jefferson Davis Highway,
Arlington, VA.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment containing material claimed to be CBI must be submitted with the CBI portions deleted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for public inspection in Room 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail:

Ingrid M. Sunzenauer,

Registration Division (TS-767C),

Office of Pesticide Programs,

Environmental Protection Agency,

401 M St., SW.,

Washington, D.C. 20460.

Office location and telephone number:

Rm. 717, CM #2,

1921 Jefferson Davis Highway,

Arlington, VA,

(703-557-7400).

SUPPLEMENTARY INFORMATION: The term "Special Review" is the name now being used by EPA for the process previously called the Rebuttable Presumption Against Registration (RPAR) process. Modifications in the process will be proposed in regulations in the near future. Until other applicable final regulations are adopted, the present Special Review will adhere to RPAR procedures now in effect and set forth in 40 CFR 162.11.

EPA has determined that a Special Review will be conducted for all pesticide products containing linuron as an active ingredient. EPA has also determined that data necessary to refine the Agency's risk assessment must be developed on an accelerated basis, and that interim precautionary labeling is required to reduce risk during the Special Review process.

Issuance of this Notice means that potential hazards associated with the use of linuron have been identified.

These hazards will be examined further to determine the nature and extent of the risk, and considering the benefits of linuron, whether such risks pose an unreasonable adverse effect.

A document entitled "Guidance for the Interim Registration of Pesticide Products Containing Linuron" (Guidance Document) has been issued. (This document is also referred to as a Registration Standard.) The Guidance Document is available to the public from the above-identified contact person. This document explains the basis of EPA's decision to start a Special Review and also contains references, background information, data requirements, and other information pertinent to the continued registration of pesticides containing linuron.

I. INITIATION OF A SPECIAL REVIEW

A. GENERAL

A pesticide product may be sold or distributed in the United States only if it is registered or exempt from registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.). Before a product will be registered, it must be shown that it can be used without "unreasonable adverse effects on the environment" (FIFRA section 3(c)(5)), that is without causing "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide." (FIFRA section 2(bb)). The burden of proving that a pesticide meets this standard for registration is on the proponent of initial or continued registration. If at any time the Agency determines that a pesticide no longer meets

this standard for registration, then the Administrator may cancel the registration under section 6 of FIFRA.

The Agency has created an administrative process for fully evaluating whether a pesticide may no longer satisfy the statutory standard for registration. This Special Review (RPAR) process provides an informal procedure through which EPA may gather and evaluate information about the risks and benefits of a pesticide's use. It also provides a means by which interested members of the public may comment on and participate in EPA's decision making process. The regulations governing this process are set forth at 40 CFR 162.11.

A Special Review (RPAR) is begun when EPA determines that a pesticide meets or exceeds one or more of the risk criteria set out in the regulations (40 CFR 162.11(a)(3)). The Agency announces its commencement of the Special Review by issuing a notice of determination for publication in the FEDERAL REGISTER, which is also called a Position Document (PD) 1. In addition, registrants of affected products will receive notice by certified mail. Registrants and other interested persons are invited to scrutinize the basis for the Agency's decision to initiate the Special Review and may submit data and information to show that the Agency's determination of risk was in error. Registrants and users may also suggest methods to reduce risks of use of the pesticide to acceptable levels. In addition to addressing risk issues, commenters are encouraged to submit evidence and discussions of the biologic, economic, social, and environmental costs and benefits of use of the pesticide.

Following the initiation of the Special Review, the pesticide use or uses of concern will enter the public participation stage of the Special Review process. Registrants and interested members of the public may submit written comments, information, or request public discussions on the Agency's proposed actions and/or other proposals for additional or alternative actions. Registrants may submit information indicating that linuron does not pose a health risk to man or the environment and/or that the benefits exceed the risks associated with linuron use. Interested members of the public may submit information concerning the risks and benefits associated with the use of linuron. The public participation stage is described in more detail in Unit V.

If risk issues are not satisfactorily resolved, EPA will proceed to evaluate the risks and benefits of linuron and to propose actions in PD 2/3 to reduce the risks. After obtaining comments from the Scientific Advisory Panel, the Secretary of Agriculture, registrants, and the public on the PD 2/3, EPA will issue a PD 4 containing EPA's final regulatory position. If EPA determines that the risks of use exceed the benefits, EPA will issue a notice of intent to cancel the registration of products intended for such use. The notice may propose cancellation or identify for specific uses certain changes in the composition, packaging, application methods and/or labeling of the product which would reduce the risks to acceptable levels.

A notice initiating a Special Review is not a notice of intent to cancel the registration of a pesticide, and a

Special Review may or may not lead to cancellation. A notice initiating a Special Review is an announcement of EPA's concern about the safety of a pesticide's use, and only after carefully considering the risks and benefits of a pesticide and determining that the pesticide will cause unreasonable adverse effects on man or on the environment, will EPA issue a notice of intent to cancel.

B. PRESUMPTION

EPA has determined that the use of pesticide products containing linuron has exceeded the risk criteria in 40 CFR 162.11(a)(3)(ii)(A). That section provides that a Special Review (RPAR) shall be conducted if the use of a pesticide "induces oncogenic effects in experimental mammalian species or in man as a result of oral, inhalation or dermal exposure...." On the basis of the scientific studies and information summarized in the Guidance Document, EPA has concluded that linuron has exceeded this risk criterion.

Specifically, data indicate that linuron induces dose-related tumors in rats. In a 2-year study male rats developed interstitial cell testicular adenomas. The frequency of these adenomas increased with the dose, and the increase was statistically significant for the two higher dose groups. Information was insufficient to indicate the extent that these tumors might be related to endocrine changes.

The 2-year mouse study showed a statistically significant increase in hepatocellular adenomas in the highest dose group for female mice, but cnly borderline statistically significant hepato-cellular adenomas for male mice and only for the lowest dose group.

The Agency used the multi-stage model to calculate a preliminary risk analysis based on the rat study. This study was used as a basis for the risk calculations because it contained the most sensitive and the most definitive dose-related increase in tumors.

The Agency calculated three estimates for the potential dietary exposure of linuron. These dietary estimates assume a uniform distribution of treated crops among the U.S. population and an average daily consumption of those crops by individuals. Although an individual's exposure could vary considerably depending upon eating habits and geographic location, the values are considered representative for the total U.S. population over a lifetime.

The first estimate was based on the tolerances and assumed that residues are at 100 percent of these levels. Tolerances are the maximum residue levels permitted on crops by the Agency. The second estimate used the maximum residues expected and is based on actual residue levels found in the field. The third estimate was based on the maximum residue expected multiplied by a rough estimate of percent crop treated. This resulted in giving a more realistic estimate of the residues which may reach humans through the diet. This estimate resulted in a dietary risk of 2×10^{-5}, which the Agency has determined is significant. The following Table 1 presents the results from all three estimates:

TABLE 1--ONCOGENIC RISK FROM DIETARY EXPOSURE TO LINURON

Assumption	TMRC[1/] (mg/day)	RISK
100 percent tolerance	0.3248	1×10^{-3}
MRE[2/]	0.0790	4×10^{-4}
MRE[2/] x percent of crop treated	0.0027	2×10^{-5}

1/ Theoretical maximum residue contribution

2/ Maximum residue expected

The Agency is aware that dietary exposure through water contamination is possible. Limited monitoring data collected in 1983 in northwestern Ohio shows the presence of linuron at low levels in surface and tap water. However, additional data are needed to assess the potential exposure and risk from linuron in drinking water. The Agency will assess this issue during the Special Review.

Non-dietary risk was also calculated. The Agency limited the non-dietary exposure analysis for linuron to the major use site, soybeans. To estimate exposure, the Agency used a surrogate study from Monsanto Company, which was based on alachlor application to soybeans. The type of formulation and method of application of alachlor are the same as for linuron. Thus, the surrogate study should provide adequate information to assess applicator exposure for linuron. The application rate for linuron is one fourth the rate of alachlor in all formulations for soybean application.

The Agency used the following assumptions to estimate linuron exposure to a soybean farmer. Potential exposure for a farmer as an applicator, mixer/loader, or both were calculated. Use by commercial applicators was not included.

1) The farmer is a 70-kg man.

2) As an applicator, the farmer may treat a 100-acre plot per day and may treat up to 600 acres per year. Consequently, he may be exposed to linuron from 1 to 6 days per year.

3) As a mixer/loader, the farmer may be exposed for approximately 15 minutes per tank and may be expected to load five tanks per day for 100 acres.

4) Respiratory exposure is not estimated because the values calculated for the inhalation exposure for alachlor are statistically insignificant compared to those for dermal exposure values.

5) The Agency assumes a lifetime exposure of 30 working years.

6) In the absence of data, the Agency assumes 100 percent dermal penetration.

The Agency calculated three exposure estimates. The first estimate represents maximum exposure because it assumes the farmer is not wearing protective clothing. In the surrogate data, dermal exposure was assessed by measuring alachlor residues on gloves or gauze pads.

The second estimate assumes the farmer is wearing protective clothing, including rubber gloves and one-piece coveralls. The Agency assumes the protective clothing reduces exposure 80 percent. Some pesticide will still filter in around the edges of the collar, cuffs, and hems. Based on the surrogate data, the gloves are assumed to reduce exposure 97 percent. Exposure to unprotected areas such as face, back of the neck, front of the neck, and "V" of the chest will also result.

The third estimate assumes the farmer is wearing protective clothing as in the second estimate, but that none

of the pesticide filters in. It is assumed that those areas protected by the clothing have 100 percent protection. However, exposure to the unprotected areas still results.

The three applicator exposure estimates are presented in the following Table 2:

TABLE 2--LINURON DERMAL EXPOSURE FOR A FARMER DURING GROUND APPLICATION TO SOYBEANS

Estimate	Units mg/kg	mg/hr	mg/kg/hr	mg/kg/lb	mg/kg/day	Annual Exposure Range[2/] (1 day/yr-6 days/yr) mg/kg/yr	Average Daily Exposure[3/] (1 day/yr-6 days/yr) mg/kg/day	
1st Estimate								
Mixer/Loader	0.21	61	0.88	0.0093	1.056	1.056 - 6.336	2.9×10^{-3}	1.7×10^{-2}
Applicator	0.007	0.45	0.0064	0.00032	0.032	0.032 - 0.192	8.8×10^{-5}	5.3×10^{-4}
Combined [1/]	-	-	-	-	1.088	1.088 - 6.528	3.0×10^{-3}	1.8×10^{-2}
2nd Estimate								
Mixer/Loader	0.024	7	0.10	0.0011	0.12	0.12 - 0.72	3.3×10^{-4}	2.0×10^{-3}
Applicator	0.0013	0.084	0.0012	0.000059	0.0058	0.0058 - 0.035	1.6×10^{-5}	9.5×10^{-5}
Combined [1/]	-	-	-	-	0.13	0.13 - 0.76	3.5×10^{-4}	2.1×10^{-3}
3rd Estimate								
Mixer/Loader	0.0058	1.7	0.025	0.00026	0.030	0.030 - 0.18	8.1×10^{-5}	4.9×10^{-4}
Applicator	0.00015	0.0097	0.00014	0.0000068	0.00066	0.00066 - 0.004	1.8×10^{-6}	1.1×10^{-5}
Combined [1/]	-	-	-	-	0.03	0.03 - 0.19	8.3×10^{-5}	5.0×10^{-4}

[1/] (Applicator mg/kg/day) + (mixer/loaders mg/kg/day)

[2/] As an applicator, the farmer may treat a 100-acre plot per day and may treat up to 600 acres per year. Consequently, he may be exposed to linuron from 1 to 6 days per year.

[3/] Annual exposure range over 365 days.

Using the multi-stage model, the Agency calculated the non-dietary oncogenic risk to farmers applying linuron. This model is a statistical means to estimate the potential lifetime risk. The figures resulting from the model vary slightly from those in the Guidance Document because they incorporate the label changes concerning protective clothing required by that document. The oncogenic risk to a farmer applying linuron to soybeans using ground application is presented in the following Table 3:

TABLE 3--ONCOGENIC RISK TO A FARMER APPLYING LINURON TO SOYBEANS USING GROUND APPLICATION

ESTIMATE	RISK (1 Day/Year)	RISK (6 Days/Year)
1st Estimate		
Mixer/loader	4×10^{-4}	2×10^{-3}
Applicator	1×10^{-5}	7×10^{-5}
Combined	4×10^{-4}	3×10^{-3}
2nd Estimate		
Mixer/Loader	5×10^{-5}	3×10^{-4}
Applicator	2×10^{-6}	1×10^{-5}
Combined	5×10^{-5}	3×10^{-4}
3rd Estimate		
Mixer/Loader	1×10^{-5}	7×10^{-5}
Applicator	3×10^{-7}	2×10^{-6}
Combined	1×10^{-5}	7×10^{-5}

In the Guidance Document the Agency determined the most reasonable estimate to be the first one, in which the farmer does not wear protective clothing. However, in the Guidance Document the Agency required registrants to revise labeling for all uses to include protective clothing. Thus, the most reasonable estimate for exposure to linuron assumes applicators are wearing protective clothing. Since linuron will likely filter in around the edges of the collar, cuffs, hem, and tops of the gloves, the second estimate is the most realistic one. In addition, it is likely that a farmer will mix, load, and apply linuron. This results in a risk of 5×10^{-5} to 3×10^{-4}. The Agency has determined that this risk is significant.

Because of the Agency's concerns, the Guidance Document also required registrants to change labeling to include a warning statement that linuron causes tumors in laboratory animals, and to indicate that linuron's classification is changed to "restricted use." Under section 4 of FIFRA this means that only certified applicators trained for and familiar with pesticide use, or persons under their direct supervision, will be able to use linuron. This restricted use classification applies to all use patterns and application techniques.

The Guidance Document requires registrants to submit approximately 50 studies which will be used to refine the Agency's risk analysis. Included are toxicology, residue chemistry and applicator exposure studies, as well as environmental fate

and product chemistry studies needed to characterize the potential for linuron to contaminate water. EPA is requiring that these studies be conducted within 6 months to 2 years, depending on the test. Most are due within one year or less and will be included in PD 2/3. Once the comments to the PD 2/3 have been analyzed, EPA will determine whether to delay the PD 4 to include the results from the longer term studies. Studies not included in the PD 4 would be reviewed when they are submitted and any necessary changes to the Agency's regulatory position would be proposed, if appropriate.

As discussed in the Guidance Document, all currently registered products will remain registered while the Special Review is in progress. Thus, the Agency is deferring final decisions on the reregistration of any products containing linuron as a sole active ingredient until the Agency concludes the Special Review. The Agency will not register any new uses of linuron until the Special Review is completed. The Agency will also not consider approving the pending requests for tolerances for linuron on sugar and lettuce or issue any new tolerances during the Special Review.

C. REBUTTAL CRITERIA

All registrants, applicants for registration, and other interested members of the public are invited to submit evidence either to support or to rebut the presumption that linuron causes oncogenic effects in rats and may cause such effects in humans. Under 40 CFR 162.11(a)(4)(iii) the presumption initiating a Special Review must be rebutted by proving,

in the case of acute and chronic toxicity criteria, "that the determination by the Agency that the pesticide meets or exceeds any of the criteria for risk was in error."

D. BENEFITS INFORMATION

The Agency will perform a benefits analysis for linuron during Special Review. The following information briefly summarizes the benefits of linuron.

E. I. duPont de Nemours, Inc. is the major producer of the technical product. Griffin Corporation and Drexel Chemical Company currently hold the other technical registrations. Estimates of domestic production are considered trade secret or proprietary under section 10 of FIFRA.

Linuron is a herbicide used mainly on soybeans, but is also federally registered for use on carrots, celery, asparagus, corn (field and sweet), cotton, parsnips, potatoes, sorghum, and winter wheat. Registered non-food sites include golf course fairways, golf tee areas, sod fields, fencerows, highway rights-of-way, streets, alleys, and vacant lots. Linuron is currently used in Michigan, under a State local need registration, for weed control in hybrid poplar plantings. In 1982, a FIFRA section 18 emergency exemption was granted to the State of Massachusetts for use of linuron on 300 acres of dry bulb onions to control galinsoga and other broadleaf weeds.

None of the alternative soybean herbicides for linuron control the same spectrum of weeds. If linuron is not used in certain situations, it is claimed that certain weeds may

not be controlled or more than one alternative may be needed to obtain equal control. Treatment costs may increase, if linuron is not available.

The most used alternative to linuron on soybeans is the triazine herbicide, metribuzin. The cost per acre for metribuzin is nearly the same. It is claimed that linuron is very effective on weeds in sandy and sandy loam soil with less than 2 percent organic matter, while metribuzin is restricted from use on such soils. Metribuzin may also not be used on certain varities of soybeans. In addition it is claimed that linuron will control the triazine-resistant weeds pigweed and lambsquarter.

The second most used alternative to linuron on soybeans is bentazon. The cost per treated acre is approximately 52 percent higher than linuron. Acifluorfen is another alternative, which costs approximately 24 percent more than linuron per acre. Both of these herbicides are more limited in their weed spectrum than linuron, have no residual control, and proper timing of application is more critical. Chloramben and Dyanap® (naptalam plus dinoseb) are the two other alternatives and cost 6 and 11 percent more per acre, respectively. Dyanap® must be applied just as soybeans are emerging and offers no residual control. These alternatives control a more limited spectrum of weeds than linuron.

In addition to submitting evidence to rebut the presumptions of risk in the Special Review, 40 CFR 162.11(a)(5)(iii) provides that a registrant or applicant "may submit evidence as to whether the economic, social and environmental benefits

of the use of the pesticide subject to the presumption outweigh the risk of use." If the presumption of risk is not rebutted, the benefits evidence submitted by registrants, applicants, and other interested persons will be considered by the Administrator when determining the appropriate regulatory action.

Registrants, applicants, or other interested persons who desire to submit benefits information should consider submitting information on the following subjects along with any other relevant information they desire to submit:

1. Identification of the biological and economic importance of linuron uses, including market studies and estimated quantities applied for those uses.

2. Identification of alternative chemical and non-chemical methods for all registered uses and application techniques, including any associated health effects and potential for water contamination.

3. Determination of the change in costs to linuron users of obtaining equivalent pest control with available substitute products or management techniques.

4. Assessment of the expected changes in level of efficacy, crop yield, crop quality, crop injury, harvesting efficiency, and environmental impacts associated with the use of alternative control measures.

5. Identification of increased or reduced risks associated with the mixing, loading, applying, and disposing of alternative chemicals, and of other hazards associated with their potential increase in use if linuron were not available.

Describe application equipment types, percent use of protective tractor cabs, protective clothing, and mixing/loading/disposing procedures for the alternative chemicals.

6. Identification of cultural practices, spray applications, and other factors that impact on farmworker exposure to linuron and any alternative cultural or Integrated Pest Management practices, which might limit the use of linuron.

II. ADDITIONAL GROUNDS FOR REVIEW

In the Guidance Document EPA is requiring, pursuant to section 3(c)(2)(B) of FIFRA, that additional product chemistry, toxicology, ecological effects, residue chemistry, and environmental fate studies of linuron be submitted. Upon receipt of these studies, they will be reviewed to determine the extent to which other adverse effects may be associated with the use of this chemical.

III. REBUTTAL SUBMISSION PROCEDURES

All registrants and applicants for registration are being notified by certified mail of the Special Review being initiated on their products containing linuron.

The registrants and applicants for registration will have 45 days from the date this notice is received or until (insert date 45 days after date of publication in the FEDERAL REGISTER) (whichever is later) to submit evidence in rebuttal to the Agency's presumption. Other interested parties may submit comments during the same period.

IV. DUTY TO SUBMIT INFORMATION ON ADVERSE EFFECTS

Registrants are required by section 6(a)(2) of FIFRA to submit any additional information regarding unreasonable adverse effects on man or the environment which comes to their attention at any time. Registrants of linuron products must immediately submit any published or unpublished information, studies, reports, analyses, or reanalyses regarding any linuron effects in animal species or humans, and claimed or verified accidents to humans, domestic animals, or wildlife which have not been previously submitted to EPA. These data should be submitted with a cover letter specifically identifying the information as being submitted under section 6(a)(2) of FIFRA. Registrants should notify EPA of any studies on linuron currently in progress, their purpose, the protocol, the approximate completion date, a summary of all results observed to date, the name and address of the laboratory performing the studies, and a statement as to whether these studies are being conducted in accordance with the Good Laboratory Practices specified in 48 FR 53946.

V. PUBLIC COMMENT OPPORTUNITY

During the time allowed for submission of rebuttal evidence, specific comments are solicited on the presumptions set forth in this Notice and in the Guidance Document. In particular, any documented episodes of adverse effects on humans or domestic animals should be submitted to the Agency as soon as possible. Any information as to any laboratory studies in progress or completed should be submitted to the

Agency as soon as possible with a statement as to whether those studies are in compliance with the Good Laboratory Practices specified in 48 FR 53946. Specifically, information on any adverse toxicological effects of linuron, its impurities, metabolites, and degradation products is solicited. Similarly, submission of any studies or comments on the benefits from the use of linuron is requested. All comments and information and analyses, which come to the attention of EPA, may serve as a basis for final determination of regulatory action following the Special Review.

All comments and information should be sent to the address given above, preferrably in triplicate, to facilitate the work of EPA and others interested in inspecting them. The comments and information should bear the identifying notation [OPP-30000/41].

During the comment period, interested members of the public or registrants may request a meeting to discuss the risk issues and methods of reducing risks. Prior to such meetings, the Agency will place an agenda and list of meeting participants in the public docket. Any member of the public interested in obtaining a copy of the agenda prior to the meeting with the Agency to discuss issues in connection with this Special Review should notify the contact person listed in this Notice. Any records pertaining to such meetings,

including minutes, agendas, and comments received will be filed under docket number OPP-30000/41.

Dated: 9/13/84

Steven Schatzow

Director,
Office of Pesticide Programs.